UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

JOINT MOTION TO AMEND SCHEDULING ORDER

Pursuant to Fed. R. Civ. P. 16 and D. Mass. L.R. 16.1, plaintiff Securities and Exchange Commission ("SEC") and defendant Richard F. Selden ("Dr. Selden") (collectively, the "Parties") hereby jointly move this Court to amend the current pretrial schedule in this action. This joint motion is the outcome of this Court's November 3, 2006 directive.

As grounds for this motion, the Parties state that on November 21, 2006, the Court in S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.) ("D.C. Court"), upon joint motion by Dr. Selden and the United States Food and Drug Administration ("FDA"), and assent by the SEC, entered a protective order directing the FDA, inter alia, to complete all document production pursuant to the D.C. Court's Order of August 16, 2006, by no later than May 15, 2007. A copy of the D.C. Court's November 21, 2006 Order is attached hereto as Exhibit A.

WHEREFORE, the Parties respectfully move this Court to modify the current pretrial schedule in this action in light of the November 21, 2006 Order. A

proposed form of Order, based on the same sequence and time intervals between the pretrial events as that in the original Scheduling Order in this action, is attached hereto as Exhibit B.

Respectfully submitted,

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Counsel for Defendant
Richard F. Selden

Dated: November 21, 2006

CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 21, 2006.

Dated: November 21, 2006

/s/ Justin J. Daniels
Justin J. Daniels

Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Miscellaneous Case No. 05-00476-RMU
v.	:	(Related Cases:
	:	Civ. No. 05-11805-NMG
RICHARD F. SELDEN,	:	Civ. No. 06-11807-NMG
	:	Pending in the United States District
Defendant,	:	Court for the District of Massachusetts)
and,	:	
FOOD AND DRUG ADMINISTRATION,	:	
Interested Party.	:	

PROTECTIVE ORDER
GOVERNING THE PRODUCTION OF FDA DOCUMENTS

Upon consideration of the Joint Motion For Protective Order Governing The Production Of FDA Documents, filed by Richard F. Selden ("Dr. Selden") and the United States Food and Drug Administration ("FDA") (collectively, the "Parties"), and upon consideration of all papers and proceedings herein, it is this 21st day of November, 2006,

ORDERED that the Joint Motion is **GRANTED**, and it is

FURTHER ORDERED that:

As negotiated by the Parties, FDA shall produce to Dr. Selden all documents within the FDA's possession, custody, or control on the terms and under the deadlines provided below, with such documents to be produced in reasonable increments on a rolling basis as they become available for production:

Subject	Negotiated FDA Production	Deadline
A. Replagal, Transkaryotic Therapies, Inc. ("TKT") and Dr. Selden.	- All documents (e.g., internal records, correspondence, e-mail and computer files) relating to Replagal (including both the BLA and all INDs), TKT or Dr. Selden, excluding: (i) documents submitted by TKT and (ii) TKT documents relating to a product other than Replagal. - All Jan. 2003 FDA Advisory Committee documents relating to Replagal, excluding: (i) documents submitted by TKT and (ii) documents publicly available at *http://www.fda.gov/ohrms/dockets/ac/cder03.html#EndocrinologicMetabolicDrugs*. - All FDA documents relating to the SEC Action or any other lawsuit involving Replagal, TKT or Dr. Selden, excluding documents submitted by Dr. Selden.	Dec. 31, 2006
B. Complete Response Letters ("CRLs").	- All CRLs (for both approved and unapproved products) issued by CBER between Jan. 1, 1998 and Dec. 31, 2002, inclusive, excluding CRLs for BLA "supplements" and BLA "non-user fee" products (see 21 U.S.C. § 379g(1)).	May 15, 2007
C. Fabrazyme.	- All documents (e.g., internal records, correspondence, e-mail and computer files) relating to Fabrazyme (including both the BLA and all INDs), excluding: (i) documents relating exclusively to CMC; (ii) documents publicly available at *http://www.fda.gov/cder/biologics/products/agalgen042403.htm*; (iii) documents generated after Apr. 23, 2003; and (iv) documents receiving special treatment (see below). - All Jan. 2003 FDA Advisory Committee documents relating to Fabrazyme, excluding documents publicly available at *http://www.fda.gov/ohrms/dockets/ac/cder03.html# EndocrinologicMetabolicDrugs*. - Fabrazyme documents receiving special treatment: (1) For Genzyme's June 2000 BLA for Fabrazyme, FDA will produce only the main reports from the sections previously indicated by Dr. Selden, and also agrees to produce on an expedited basis any additional exhibits or attachments based on any reasonable request by Dr. Selden. (2) For Genzyme's written responses to FDA's CRLs for Fabrazyme, FDA will produce only Genzyme's substantive responses to each of the questions/items in the CRL, and also	May 15, 2007

Subject	Negotiated FDA Production	Deadline
	agrees to produce on an expedited basis any additional exhibits or attachments based on any reasonable request by Dr. Selden.	
D. Internal review guidelines.	- CBER's New Reviewer training materials available for reference or use during the period June 1, 2000 through May 31, 2001. In addition, FDA also agrees to produce on an expedited basis any additional sections of the New Reviewer materials for the periods Jan. 1, 1998 through May 31, 2000 and June 1, 2001 through Apr. 23, 2003, based on any reasonable request by Dr. Selden. - CBER's internal review manuals available for reference or use during the period June 1, 1998 through Apr. 23, 2003. - All other guidelines, manuals, templates, and training materials for CBER review of BLAs, INDs, trials, protocols, etc. that were available for reference or use during the period June 1, 2000 through Dec. 31, 2002.	May 15, 2007
E. Record retention schedules.	- FDA's Headquarters Record Control Schedule, last updated on Dec. 31, 1989, which FDA represents was and is the applicable record retention schedule for 1990 to present.	Production Complete
F. FDA guidance on public disclosure of status.	- The FDA states that it has no responsive documents.	N/A
G. FDA/SEC coordination.	- All responsive documents.	Dec. 31, 2006
H. Remaining Requests.	- No production necessary.	N/A

[12345678]tion, the productions referenced above shall be governed by the following terms and conditions:

1. All documents produced pursuant to this Order may be used only in connection with S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass.) ("SEC Action") and S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.). Documents produced pursuant to this Order shall not be disclosed or revealed in any way outside of those actions.

2. Some categories of documents to be produced pursuant to this Order contain non-public information, including confidential commercial or financial information, submitted to FDA by third parties. FDA will produce such documents pursuant to the terms of this Order and in accordance with applicable law (see, e.g., 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. § 20.61) and FDA procedures.

3. In addition to the restrictions set forth in paragraph 1, above, if the FDA produces documents containing unredacted privileged or confidential third-party commercial or financial information (as those terms are defined in 21 C.F.R. § 20.61), such documents shall be governed by the following additional terms:

a. Upon production of such documents, the FDA shall notify Dr. Selden in writing which documents are subject to this paragraph 3.

b. The right of access to documents subject to this paragraph 3 is limited to the following persons: (a) attorneys and parties in the SEC Action; (b) medical and analytical experts, not employed by any drug manufacturer, whose review of the material is deemed essential to the preparation or presentation of the defense in the SEC Action; and (c) such law

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1 See 10/28/05 Subpoenas, Sch. A, Request Nos. 1, 2, 4, 6 & 8.

2 See id. No. 3.

3 See id. Nos. 1, 2 & 7.

4 See id. No. 9.

5 See id. No. 10.

6 See id. No. 12.

7 See id. No. 13.

8 See id. Nos. 5 & 11.

clerks, paralegals, secretaries, and consultants whose review of this material is deemed essential to the preparation or presentation of the defense in the SEC Action.

c. Prior to review of the material described in this paragraph 3, each person who is not a government employee or attorney in the SEC Action shall sign and date a copy of the following statement:

> I acknowledge access to confidential material ("protected material") received pursuant to a Protective Order issued in the miscellaneous civil action entitled S.E.C. v. Richard F. Selden, Misc. Case No. 05-00476-RMU (D.D.C.), for purposes of production in the related action entitled S.E.C. v. Richard F. Selden, Civ. No. 05-11805-NMG (D. Mass.) ("SEC Action"). I certify my understanding that I will be in violation of that Protective Order and will be subject to contempt of court proceedings if I do not abide by the following requirements:
>
> All notes pertinent to the protected material must, when not in my personal custody, either be returned to another person authorized under the Protective Order to review the protected material, or must be stored in a locked repository (such as a locked desk drawer or locked file) for which I must maintain personal custody of keys or combinations thereto.
>
> I may grant access to my notes only to those individuals who are authorized under the Protective Order to review the protected material.
>
> I must return all notes pertinent to the protected material to the attorneys who provided access to the material upon termination of this case, when my need for the information with respect to this case no longer exists, or upon order of the Court, whichever occurs first.
>
> I must report in writing to the Court in the SEC Action all incidents in which unauthorized persons might have gained access to my notes about the protected material.

> I must not release, publish, disclose or use for any purpose (other than for the preparation or testimony in any hearing or trial in the SEC Action) this protected material, and specifically any of the facts contained therein or any information derived therefrom.

One copy of each such statement shall be provided to counsel for the FDA within 30 days after the conclusion of the SEC Action.

d. Any submissions to this Court or to the Court in the SEC Action that refer to or describe material subject to this paragraph 3 are to be marked "Confidential FDA Material" and are not to be placed in the public file or on public record without the prior written consent of the FDA.

e. All material subject to this paragraph 3 must either be returned to counsel for the FDA or destroyed at such time as it is not further needed in the SEC Action, at the conclusion of the SEC Action, or upon order of the court, whichever occurs first. If the persons in possession of such material opt to destroy it, they shall certify in writing to FDA, within five (5) days of destruction, that all such material has been destroyed.

6. If a document is redacted or withheld from production on the basis of the deliberative process privilege,[9] the FDA shall, within 30 days of production (in the case of redaction) or decision to withhold (in the case of withholding) provide Dr. Selden with a "Vaughn index"[10] covering such documents. With respect to documents redacted or withheld on bases other than the deliberative process privilege, the FDA shall provide its Vaughn index within 90 days.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

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9 See Judicial Watch, Inc. v. FDA, 449 F.3d 141, 150-52 (D.C. Cir. 2006).

10 See Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973).

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Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

[PROPOSED] AMENDED SCHEDULING ORDER

The deadlines contained in the Scheduling Order entered January 13, 2006, as amended by Electronic Order on March 24, 2006 and by the Court in open court on November 3, 2006, are further amended as follows:

1. Written discovery requests are to be served by April 13, 2007, and answers are to be served by May 14, 2007;

2. All fact depositions are to be completed by September 13, 2007;

3. All trial experts by plaintiff are to be designated and disclosure of information contemplated by Fed. R. Civ. P. 26(a)(2) by October 12, 2007; all trial experts by defendant are to be designated and disclosure of information contemplated by Fed. R. Civ. P. 26(a)(2) by December 13, 2007; plaintiff expert depositions are to be completed by November 13, 2007; defendant expert depositions are to be completed by January 14, 2008;

4. All dispositive motions, including motions for summary judgment, are to be filed by February 29, 2008;

5. Discovery is to be completed by September 13, 2007, unless shortened or enlarged by Order of this Court; and

6. A final pretrial conference will be held on _____ to be notified by the Court, and must be attended by trial counsel. Counsel shall be prepared to commence trial as of _____.

Dated: _____

_____
UNITED STATES DISTRICT JUDGE